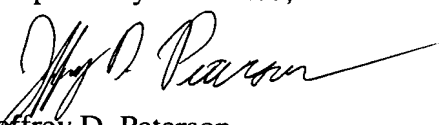
REMARKS

With the entry of the above amendments, claims 1, 3-8, and 10-55 are pending in the application. Claims 3-8, 10-20, 22-28, 30-32, and 36-41 have been amended to correct errors in the preamble of the claims, as well as the dependency of the claims. Claim 3 has additionally been amended to include liver cancer to the list of cancers inhibited by the method of claim 3. New claims 42-55 are dependent claims which add further limitations to claims 3, 10, 14 or 29. No new matter has been added by these amendments.

Applicants respectfully submit that the claims are in condition for allowance and solicit an early notice of allowance. In the event that there are any issues which can be expedited by telephone conference, the Examiner is invited to telephone the undersigned at the number indicated below.

Respectfully submitted,



Jeffrey D. Peterson
Reg. No. 49,038

File No. 017620-9335
Michael Best & Friedrich LLP
One South Pinckney Street
P. O. Box 1806
Madison, WI 53701-1806
(608) 257-3501

VERSION WITH MARKINGS TO SHOW CHANGES MADE

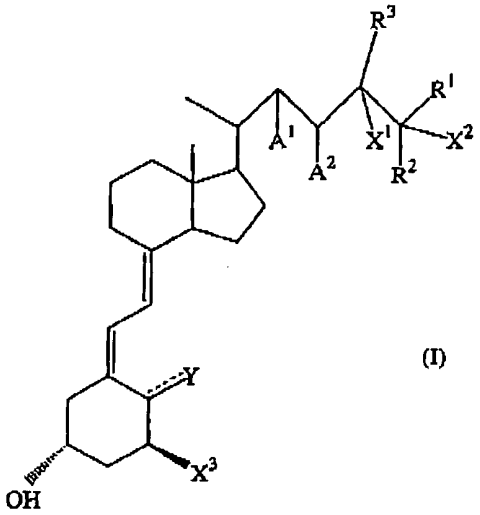
IN THE SPECIFICATION

[0001] This application is a continuation-in-part of U.S. application Serial No. [09/891,763] 09/891,814 filed June 26, 2001, which is a continuation-in-part of U.S. application Serial No. 09/596,149, filed February 23, 1998, which is a [division] divisional of U.S. application Serial No. 08/781,910, filed December 30, 1996, now U.S. Patent 5,763,429, all of which are incorporated herein by reference.

IN THE CLAIMS

3. (Once Amended) A method in accordance with [The method of] claim 1, wherein the malignant cells are associated with cancers of the breast, colon, prostate, lung, neck and head, pancreas, endometrium, bladder, cervix, testes, ovaries, and liver, squamous cell carcinoma, myeloid and lymphocytic leukemia, lymphoma, medullary thyroid carcinoma, melanoma, multiple myeloma, retinoblastoma or sarcomas of the soft tissues and bone.

4. (Once Amended) A method in accordance with [The method of] claim 1 [2], wherein the hypocalcemic vitamin D is a compound represented by formula (I):

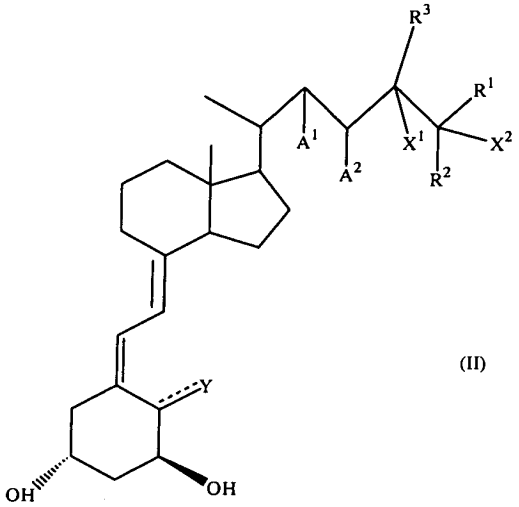


(I)

wherein A^1 and A^2 each are hydrogen or together represent a carbon-carbon bond, thus forming a double bond between C-22 and C-23; R^1 and R^2 are identical or different and are hydrogen, lower alkyl, lower fluoroalkyl, O-lower alkyl, lower alkenyl, lower fluoroalkenyl, O-lower alkenyl, O-lower acyl, O-aromatic acyl, lower cycloalkyl with the proviso that R^1 and R^2 cannot both be an alkenyl group, or taken together with the carbon to which they are bonded, form a C_3-C_8 cyclocarbon ring; R^3 is lower alkyl, lower alkenyl, lower fluoroalkyl,

lower fluoroalkenyl, O-lower alkyl, O-lower alkenyl, O-lower acyl, O-aromatic acyl or lower cycloalkyl; X^1 is hydrogen or hydroxyl, or, taken with R^3, constitutes a bond when R^3 is an alkenyl group, and X^2 is hydrogen or hydroxyl, or, taken with R^1 or R^2, constitutes a double bond, and X^3 is hydrogen or hydroxyl provided that at least one of X^1, X^2 and X^3 is hydroxyl; and Y is a methylene group if the bond to Y is a double bond or is a methyl group or hydrogen if the bond to Y is a single bond.

5. (Once Amended) A method in accordance with claim 1 [2] wherein the hypocalcemic vitamin D compound is a compound of formula (II):



(II)

wherein A^1 and A^2 each are hydrogen or together represent a carbon-carbon bond, thus forming a double bond between C-22 and C-23; R^1 and R^2 are identical or different and are hydrogen, lower alkyl, lower fluoroalkyl, O-lower alkyl, lower alkenyl, lower fluoroalkenyl, O-lower alkenyl, O-lower acyl, O-aromatic acyl, lower cycloalkyl with the proviso that R^1 and R^2 cannot both be an alkenyl group, or taken together with the carbon to which they are bonded, form a C_3-C_8 cyclocarbon ring; R^3 is lower alkyl, lower alkenyl, lower fluoroalkyl, lower fluoroalkenyl, O-lower alkyl, O-lower alkenyl, O-lower acyl, O-aromatic acyl or lower cycloalkyl; X^1 is hydrogen or hydroxyl, or, taken with R^3, constitutes a bond when R^3 is an alkenyl group, and X^2 is hydrogen or hydroxyl, or, taken with R^1 or R^2, constitutes a double bond, and Y is a methylene group if the bond to Y is a double bond or is a methyl group or hydrogen if the bond to Y is a single bond.

10. (Once Amended) A method in accordance with [The method as claimed in] claim 1 [9] wherein the amount of active vitamin D is a high dose which is between about 10μg to about 200μg.

11. (Once Amended) A method in accordance with [The method of] claim 10 [9] wherein the amount of the vitamin D compound is administered parenterally or orally in combination with a pharmaceutically acceptable carrier.

12. (Once Amended) A method in accordance with [The method of] claim 11 wherein the amount of vitamin D compound is administered parenterally.

13. (Once Amended) A method in accordance with [The method of] claim 12 wherein the amount of vitamin D compound is administered intravenously.

14. (Once Amended) A method in accordance with [The method of] claim 1 [9] wherein the amount administered is from about 10 μg to about 200 μg/dose given once per week to once every 12 weeks.

15. (Once Amended) A method in accordance with [The method of] claim 1 wherein the active vitamin D lacks a hydrocarbon moiety at the C-24 position.

16. (Once Amended) A method in accordance with [The method of] claim 15 wherein the active vitamin D is 1α,25-dihydroxyvitamin D_3 or 1α-dihydroxyvitamin D_3.

17. (Once Amended) A method in accordance with [The method of] claim 16 wherein the amount of the vitamin D compound is administered parenterally or orally in combination with a pharmaceutically acceptable carrier.

18. (Once Amended) A method in accordance with [The method of] claim 17 wherein the amount of vitamin D compound is administered parenterally.

19. (Once Amended) A method in accordance with [The method of] claim 18 wherein the amount of vitamin D compound is administered intravenously.

20. (Once Amended) A method in accordance with [The method of] claim 16 wherein the amount is administered is from about 10 μg to about 200 μg/dose given once per week to once every 12 weeks.

22. (Once Amended) A method in accordance with [The method of] claim 21 wherein an amount of the active vitamin D compound and an amount of the agent are episodically co-administered to a human cancer patient, the amount of the active vitamin D effective to inhibit the hyperproliferation of the neoplastic cells.

23. (Once Amended) A method in accordance with [The method of] claim 22 wherein the agent is an antineoplastic agent.

24. (Once Amended) A method in accordance with [The method of] claim 23 wherein the antineoplastic agent is given episodically and the active vitamin D is given concurrently with the antineoplastic agent.

25. (Once Amended) A method in accordance with [The method of] claim 23 wherein the antineoplastic agent is an antimetabolite, an antimicrotubule agent, an alkylating agent, a platinum agent, an anthrocycline, a topisomerase inhibitor, an antibiotic, any other antineoplastic agent or combinations thereof.

26. (Once Amended) A method in accordance with [The method of] claim 22 wherein the agent is an antihypercalcemic agent.

27. (Once Amended) A method in accordance with [The method of] claim 26 wherein the antihypercalcemic agent is a bisphosphonate.

28. (Once Amended) A method in accordance with [The method of] claim 22 wherein an active vitamin D compound, an antineoplastic agent and an antihypercalcemic agent are co-administered.

30. (Once Amended) A method in accordance with [The method of] claim 29 wherein an amount of the active vitamin D compound is episodically administered to a human patient suffering from the hyperproliferative disease, the amount being effective to inhibit hyperproliferation of the cells.

31. (Once Amended) A method in accordance with [The method of] claim 30 wherein the amount is a high dose which is between about 10 μg and about 200 μg.

32. (Once Amended) A method in accordance with [The method of] claim 30 wherein the hyperproliferative disease is psoriasis.

36. (Once Amended) A kit in accordance with [The kit of] claim 35 wherein the agent is an antineoplastic agent.

37. (Once Amended) A kit in accordance with [The kit of] claim 36 wherein the vitamin D compound and the antineoplastic agent are formulated for parenteral administration.

38. (Once Amended) A kit in accordance with [The kit of] claim 36 wherein the vitamin D compound and the antineoplastic agent are manufactured physically separately and are intended for time-sequential co-administration.

39. (Once Amended) A kit in accordance with [The kit of] claim 35 consisting essentially of

a) an active vitamin D compound;

b) an antineoplastic agent; and

c) instructions effective to perform the method of claim 22.

40. (Once Amended) A kit in accordance with [The kit of] claim 35 consisting essentially of

a) an active vitamin D compound;

b) an antineoplastic agent;

c) an antihypercalcemic agent; and

d) instructions effective to perform the method of claim 22.

41. (Once Amended) A kit in accordance with [The kit of] claim 35, wherein the active vitamin D compound is present in dosage of between about 10 μg and about 200 μg.